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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/611,652	07/07/00	ZEMAN	R 001290.09119

HM22/0703
PITNEY HARDIN KIPP & SZUCH LLP
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NEW YORK NY 10017

EXAMINER

HUI, S

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 07/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/611,652

Applicant(s)

ZEMAN ET AL.

Examiner

San-ming Hui

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claims 1-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10, drawn to a method of rehabilitation following spinal cord injury, classified in class 514, subclass 555, 649, 650, and 651.
- II. Claims 11-20 (including claims 15, 18, and 20 insofar as they are intended to be drawn to a composition), and 32-36 (including claim 36 insofar as it is intended to be drawn to a composition), drawn to a composition comprising β_2 -adrenergic agonist, classified in class 514, subclass 555, 649, 650, and 651.
- III. Claims 21-31, drawn to a method of treating neurological conditions, classified in class 514, subclass 555, 649, 650, and 651.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The invention of Group I functions to rehabilitate following spinal cord injury and the invention of Group II functions to treat neurological conditions.

Inventions II, and I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1)

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the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the rehabilitation following spinal cord injury for using the product as claimed can be practiced with another materially different product such as a composition containing 4-aminopyridine.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Election of species

Claims 1-3, 6, 11-13, 16, 21-24, 27, and 32-34 are generic to a plurality of disclosed patentably distinct species comprising β_2 -adrenergic agonists. For example, if the β_2 -adrenergic agonist is clenbuterol, it is classified class 514, subclass 649; if the β_2 -adrenergic agonist is salmeterol, it is classified class 514, subclass 651; if the β_2 -adrenergic agonist is metaproterenol, it is classified class 514, subclass 555; if the β_2 -adrenergic agonist is fenoterol, it is classified class 514, subclass 650.

In addition, if the invention of Group III is elected, the neurological conditions recited in claims 21-31 are a generic representation of a multiple patentably distinct species such as for example, neural degeneration, loss of locomotor function, and spinal cord injury. Applicant is required to elect a single disorder. These disorders have different etiologies, and different treatment for example, neural degeneration could be caused by aging, trauma, or genetic (as seen in the case of Parkinson diseases and Alzheimer's disease), also it is well-known that the treatment of Parkinson's disease and

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Alzheimer's disease are different. Further, loss of locomotor function may be treated by physical therapy or pharmacological therapy. Finally, spinal cord injury can be treated by surgical intervention, or pharmacological therapy such as steroid and/or potassium channel modulators. Therefore the field of search for all the disorders is divergent.

Due to the structural diversity in active compounds herein and the different and unrelated natures of the neurological conditions encompassed by the claims, the search for all species presents an undue burden on the office.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of β_2 -adrenergic agonist. Applicant is also required under 35 U.S.C. 121 to elect a single disclosed species of a neurological conditions if Group III is elected, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call was made to Mr. Mathew Siegal on May 28, 2001 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Monday to Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moëzie, J.D., can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

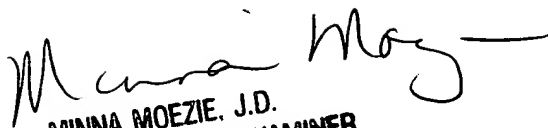
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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San-ming Hui
June 28, 2001


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SUPERVISORY PATENT EXAMINER
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